

REMARKS

Claims 42-44, 47-55, 57, 59-64 and 66-69 currently appear in this application. The Office Action of August 11, 2004, has been carefully studied. These claims define novel and unobvious subject matter under Sections 102 and 103 of 35 U.S.C., and therefore should be allowed. Applicants respectfully request favorable reconsideration, entry of the present amendment, and formal allowance of the claims.

Allowable Subject Matter

Claims 41-44 would be allowable if rewritten in independent form.

Claim 41 has now been rewritten as claim 69, which new claim incorporates all of the limitations of claim 39, from which claim 41 depended, omitting the limitations of claim 40 that the denaturing conditions are selected from the group consisting of heat-treatment, pH change, change in ionic strength, chromatin denaturing agent, and combinations thereof. All claims, which previously depended from claims 39 or 41, have now been amended to depend from claim 69.

Claims 39, 40, 47 and 49-64 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a process of reconstructing a nonhuman mammalian embryo comprising transferring into an enucleated metaphase II oocyte a donor cell or donor cell nucleus of the

same species as the oocyte, wherein the chromatin with the nucleus had been subjected to thermal denaturation prior to transfer to the oocyte, is said not to provide enablement for the process wherein the chromatin had been denatured by any other process.

This rejection is respectfully traversed. Claim 41 has been rewritten as claim 69, which claim is believed to be patentable. Since the remaining claims in the present application ultimately depend from claim 69, it is respectfully submitted that there is enablement for the methods as claimed.

Claims 48 and 65-68 are rejected under 35 U.S.C. 112, first paragraph, for containing subject matter which was not described in the specification such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

This rejection is respectfully traversed. Claims 48 and 65-68 have been amended to depend from new claim 69, which is believed to be allowable.

Additionally, the Examiner alleges that dead or dying cells have chromosomal degradation and will not successfully produce a developing embryo. In support of the feasibility of a nuclear transfer from a donor non-living cell

and a viable recipient cell, copies of the following two papers are submitted herewith:

Loi et al., *Biology of Reproduction*, 67, 126-132 (2002). Loi et al., *Nature Biotechnology* 29, 962-964 (2001). Loi and Cappai demonstrate in *Nature Biotechnology* that post-mortem cells can indeed be used in nuclear transfer techniques, and successfully produced a viable offspring.

Moreover, one could consider that the heat-treated donor cells in the present invention are actually "non-living" cells. Nevertheless, these cells prove to be capable of generating viable embryos and viable offspring as demonstrated in the present application and in the Loi et al. *Biology of Reproduction* article. Accordingly, claim 50 should be allowable.

With respect to claims 64-68, the Examiner alleges that the evidence of record does not make clear that live births occurred as a result of the claimed method. However, the article from *Biology of Reproduction* 2002 submitted herewith, provides indisputable evidence that by following the method described in the section "Materials and Methods", which is the same method disclosed and claimed in the present invention, the authors were actually able to produce live mammalian offspring, namely, four living female lambs (see page 129, right column, *et seq.*)

Claims 39, 45, 50-54 and 56-58 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

This rejection is respectfully traversed. Claims 39, 45, 46, 56 and 58 have been cancelled. Claim 50, which recites dead or dying cells, has been demonstrated above to be operable. Claims 52-54 has been amended to recite -comprises- rather than "includes." Claim 54 has also been amended to substitute -gene-for "group." Claims 56-58 have been cancelled.

It is noted that there are no art rejections.

In view of the above, it is respectfully submitted that the claims are now in condition for allowance, and favorable action thereon is earnestly solicited.

Respectfully submitted,

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